

510(k) SUMMARY

PhotoMedex, Inc.

LaserPro 810, 940 and 980 Surgical Diode Laser Systems

OCT 28 2008

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
147 Keystone Drive
Montgomeryville, PA, 18936
- *Contact Person:* Alfred Intintoli
- *Date Prepared:* September 15, 2008 (Revised October 14, 2008)

2. DEVICE NAME

- *Classification name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
- *Common or usual name:* Diode Laser
- *Trade or proprietary name:* LaserPro Diode Surgical Laser System

3. PREDICATE DEVICES

Diode Surgical Laser Systems

- PhotoMedex LaserPro 810, 940 & 980 Surgical Diode Laser Systems: **Cleared via K042211, K040294**
- Biolitec Ceralas D980 (Models D15, D25): **Cleared via K072779**
- CeramOptec Ceralas (Models D10-60): **Cleared via K001975**
- B&W Tek BWF-5 Medical Laser Series: **Cleared via K062363**
- Premier Aurora Laser System: **Cleared via K954316**
- SLT Thermalite 810, 940, & 980 Laser Systems: **Cleared via K952661**
- Osyris Pharaon Lipo : **Cleared via K073617**
- Palomar Aspire: **Cleared via K080567, K081416**

Other Laser Systems

- Cynosure SmartLipo ND:YAG Laser System: **Cleared via K062321**
- New Star Lasers, Inc CoolTouch NS160 Nd:Yag Surgical Laser : **Cleared via K072751**

4. DEVICE DESCRIPTION and DEVICE MODIFICATIONS

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems are designed to provide laser power at wavelengths of 810nm, 940nm, and 980nm, depending on model, which can be used for the procedures indicated in the next section of this summary. These devices have been cleared previously via K 040294 and K042211. Differences between the cleared and modified device are limited to:

- ❖ Addition of **Laser Assisted Lipolysis** to the indications of use of the LaserPro 980 Surgical Diode Laser Systems previously cleared via K040294 and K042211.
- ❖ Addition of **several other indications for use** to the indications for use of the LaserPro 810, 940 & 980 Surgical Diode Laser Systems previously cleared via K040294 and K042211.

The system is comprised of the following main components:

- A laser console/cabinet with fiber port to accept SMA-905 connectors.
- Display panel with soft-touch keypad control and separate Emergency Off button.
- Laser system microprocessor control electronics with operating software
- A detachable covered footswitch.

5. INDICATIONS FOR USE

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only).

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: orthopedics.

6. SUBSTANTIAL EQUIVALENCE

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, when used in conjunction with cleared delivery accessories, share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the predicate devices listed above.

7. SAFETY AND EFFECTIVENESS

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems are designed, tested and manufactured in accordance with both mandatory and voluntary Standards ensuring when used with marketed cleared delivery systems identified to be compatible, they are considered both safe and effective for the medical applications indicated. The addition of Laser Assisted Lipolysis and the several other indications for use to the previously cleared indications do not raise new issues of safety and effectiveness as the LaserPro 810, 940 and 980 Surgical Diode Laser Systems are substantially equivalent to the predicate devices listed above which have previously demonstrated their clinical effectiveness.

8. CONCLUSIONS

PhotoMedex believes that the (minor) modification to the LaserPro 810, 940 and 980 Surgical Diode Laser Systems are substantially equivalent to, and are safe and effective as the legally marketed identified predicate devices listed above, in that they share identical mechanisms for laser energy delivery and indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PhotoMedex, Inc.
% Mr. Alfred Intintoli
Director, Product Development
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

OCT 28 2008

Re: K082721

Trade/Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: October 14, 2008

Received: October 16, 2008

Dear Mr. Intintoli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Alfred Intintoli

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082721

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only).

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: orthopedics.

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems are indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, orthopedics, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only) as follow:

Gastroenterology

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include:

- hemostasis of esophageal varices;
- palliation of malignant dysphagia;
- palliative ablation of obstructive neoplasms;
- hemostasis of colonoscopy.
- hemostasis of upper and lower GI bleeding (810 nm or 980 nm only);
- excision and vaporization of colorectal carcinoma (810 nm or 980 nm only);
- excision of polyps (810 nm or 980 nm only).

*** Page 1 of 7 (Indications For Use Continued on Next Page; 7 pages total) ***

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Over-The Counter Use _____
DR

(Division Sign-Off) Optional Format 1-2-96)

Division of General, Restorative,
and Neurological Devices

510(k) Number K08271

Indications for Use Statement

510(k) Number: K082721

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

Continued from previous page:

Neurosurgery

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include:

- tumors adjacent to the spinal cord;
- tumors adjacent to the cortex.

General Surgery, Aesthetic (Dermatology and Plastic Surgery), and Podiatry

Treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein.

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include:

- Laparoscopic
 - appendectomy;
 - cholecystectomy;
 - bowel resection.
- Open
 - mastectomy;
 - reduction mammoplasty;
 - breast biopsy;
 - rectal and anal hemorrhoidectomy;
 - bowel resection;
 - colectomy;
 - cholecystectomy;
 - liver resection;
 - condyloma;
 - thyroidectomy;

*** Page 2 of 7 (Indications For Use Continued on Next Page; 7 pages total) ***

[Signature]
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**Division of General, Restorative,
and Neurological Devices**

510(k) Number 1082721

Indications for Use Statement

510(k) Number: K082721

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

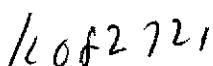
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- thoracotomy;
- cavernous hemangioma;
- Open (810 nm or 980 nm only)
 - matrixectomy;
 - excision of neuromas;
 - excision of perifungal & subungual warts;
 - excision of plantar warts;
 - excision of keloids
 - excision of cutaneous lesions;
 - debridement of decubitus ulcer;
 - hepatobiliary tumors;
 - dermabrasion;
 - vaporization & hemostasis of capillary hemangioma;
 - excision, vaporization, & hemostasis of abdominal tumors;
 - excision, vaporization & hemostasis of rectal pathology;
 - pilondial cystectomy;
 - herniorrhaphy;
 - adhesiolysis;
 - parathyroidectomy;
 - thyroidectomy;
 - resection of organs;
 - debridement of wounds
 - photocoagulation of telangiectasia of the legs and face;
 - photocoagulation of vascular lesions of the face and extremities.

*** Page 3 of 7 (Indications For Use Continued on Next Page; 7 pages total) ***


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**Division of General, Restorative,
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Indications For Use:

Continued from previous page:

Genitourinary (Urology)

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include:

- Transurethral
 - transurethral incision of the prostate (TUIP);
 - bladder tumors;
 - bladder neck incisions;
 - removal of bladder neck obstructions (810 nm or 980 nm only);
 - urethral strictures;
 - exterior sphincterotomy.
 - vaporization of urethral tumors (810 nm or 980 nm only).
- Laparoscopic
 - lymphadenectomy.
- Open
 - condyloma;
 - circumcision
 - benign and malignant lesions of external genitalia.

Thoracic Surgery

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include:

- pulmonary resection;
- coagulation of blebs and bullae;
- adhesiolysis;
- pericardectomy
- mediastinal and thoracic lesions and abnormalities;
- mediastinal lymph node dissection;
- thoracotomy.

*** Page 4 of 7 (Indications For Use Continued on Next Page; 7 pages total) ***

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**Division of General, Restorative,
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510(k) Number

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Indications For Use:

Continued from previous page:

Gynecology (GYN)

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include:

- Laparoscopic
 - excision/lysis of adhesions;
 - endometrial lesions, including ablation of endometriosis;
 - laparoscopic assisted hysterectomy (LAVH);
 - laser uterosacral nerve ablation (LUNA);
 - myomectomy;
 - ovarian cystectomy;
 - ovarian drilling;
 - tubal fimbrioplasty;
 - appendectomy;
 - menorrhagia (810 nm or 980 nm only).
- Open
 - conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN;
 - condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions.
- Intrauterine
 - fibroids/polyps/adhesions;
 - resection of septum.

*** Page 5 of 7 (Indications For Use Continued on Next Page. 7 pages total.)


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510(k) Number 1082721

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510(k) Number: K082721

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Indications For Use:

Continued from previous page:

Pulmonology

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include:

- tracheal bronchial lesions.
- tracheobronchial malignancy or stricture; (810 nm or 980 nm only)
- benign and malignant pulmonary obstruction; (810 nm or 980 nm only)
- endoscopic pulmonary applications. (810 nm or 980 nm only)

Ophthalmology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include:

- Oculoplastics
 - open DCR;
 - endo-nasal DCR;
 - tumor excision and biopsy;
 - eyelid reconstruction;
 - blepharoplasty.

Orthopedics

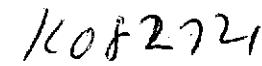
The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures and arthroscopy; and the hemostasis of soft tissue in arthroscopy. Applications include:

- Open
 - dissect and coagulate.

*** Page 6 of 7 (Indications For Use Continued on Next Page; 7 pages total) ***


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**Division of General, Restorative,
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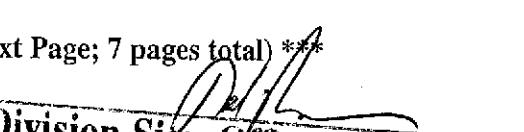
Otolaryngology (ENT)

The hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include:

- Nasal/Sinus
 - turbinectomy and turbinate reduction/ablation;
 - polypectomy of nose and nasal passages;
 - ethmoidectomy;
 - meatal antrostomy;
- Laryngo-tracheal
 - removal of vocal cord/fold nodules, polyps and cysts;
 - arytenoidectomy;
 - tracheal stenosis;
- Oropharyngeal
 - uvulopalatoplasty (LAUP, laser UPPP);
 - tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil;
 - hemi glossectomy;
- Head & Neck
 - tumor resection on oral, subfacial and neck tissues;
 - parathyroidectomy;
 - thyroidectomy.

Laser Assisted Lipolysis (980 nm only)

*** Page 7 of 7 (Indications For Use Continued on Next Page; 7 pages total) ***


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Division of General, Restorative,
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